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EXAMINER

FOX, DAVID T

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 12/11/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 69/761,167	Applicant(s) Gagerty
Examiner FOX	Group Art Unit 1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 7/29/02
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-32 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☒ Claim(s) 1-7 and 20 is/are allowed.
- ☒ Claim(s) 8-19 and 21-32 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

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Part of Paper No. 8

*U.S. GPO 1998-454-457/97505

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The claim amendments of 29 July 2002 have overcome all outstanding rejections under 35 USC 112, except as indicated below. However, new grounds of rejection under 35 USC 112, first and second paragraphs, are set forth below. The delay in prosecution is regretted.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendment of 29 July 2002 to the specification has not been entered, because there was no port of entry on page 33 of the specification at line 35 corresponding to the paragraph to be amended.

Claims 5-8, 10-19, 21 and 23-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12, 16, 25 and 29, and dependent claims 13-15, 17-19, 26-28, and 30-32, are indefinite in their recitation of "plant according to claim 2 [or 20] further comprises...transgenes [or genes transferred by backcrossing]". Since the claims are initially drawn to plants with defined characteristics and genotypes (such as claim 2) which exclude the presence of transgenes or backcrossed genes, it is confusing to characterize these plants as comprising additional genes. The dependent claims fail to further limit the claims from which they depend.

The Examiner acknowledges that Applicant has amended the claims as directed by the Examiner in the previous office action. However, it is now considered that the claims should be drafted in terms of methods of making a plant comprising transforming the exemplified plant, and

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the products can be claimed in a product-by-process format. See the suggested claims faxed by Supervisory Patent Examiner Amy Nelson on 2 August 2002 in copending and commonly owned application Serial No. 09/490,666.

Claims 11, 15, 19, 24, 28 and 32 remain indefinite in their recitation of "very high", "above average", "very good", "low", "stong", "moderate" and "suited" as these terms are unduly narrative and imprecise, and do not clearly set forth the degree of expression of the claimed characteristics or clearly characterize the corn plants exhibiting them.

Claims 10, 14, 18, 23, 27 and 31, and dependents, remain indefinite in their recitation of "[t]he maize plant breeding program of claim 9 [or 13 or 17 or 22 or 26 or 30]", which is confusing, since the previous claims are drawn to methods rather than breeding programs.

Claims 8 and 21 remain indefinite for characterizing the male fertile plant of claim 2 [or claim 20] as male sterile. See the suggested amendment for claims 12, 16, 25 and 29 above.

Claims 8-19 and 21-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 12, 15, 25, 28, and dependents are broadly drawn to any transgenic plant which contains any heterologous transgene of any sequence conferring any trait, and methods of using the transgenic plants. Claims 8, 16, 19, 21, 29, 32 and dependents are broadly drawn to any "single gene conversion" plant comprising one or more traits introgressed into the claimed variety

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by backcrossing or other traditional means, and methods of using these plants. Claims 9-11, 13-15, 17-19, 22-24, 26-28 and 30-32 are also broadly drawn to any plant produced by crossing the exemplified hybrid line with any of a multitude of non-exemplified plants, or any descendant of the exemplified cultivar obtained by using that cultivar as one parent in a series of undisclosed crosses for an undisclosed number of generations and with undisclosed breeding partners. These claims are also broadly drawn to methods of using the transgenic plants, single gene conversion plants, or descendant plants.

No guidance has been provided for the description or characterization of a multitude of heterologous coding sequences conferring a multitude of traits. In addition, no guidance has been provided for the introgression of any trait from a multitude of non-disclosed and uncharacterized parentals into the claimed variety, wherein said introgression should result in successful expression of the desired trait but should not interfere with the expression of the remaining traits whose combination confers patentability to the instantly exemplified variety, and which introgression should not introduce unwanted linked genetic material into the exemplified cultivar which would disrupt its patentably unique genetic complement. In addition, no guidance has been provided regarding the genetic or morphological characteristics of any of a multitude of breeding partners, or the resultant progeny.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention “requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter

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sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” *Id.*

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products, any method of using them would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111).

Claims 8, 12-19, 21 and 25-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 12, 15, 25, 28, and dependents are broadly drawn to any transgenic plant which contains any heterologous transgene of any sequence conferring any trait, and methods of using

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the transgenic plants. Claims 8, 16, 19, 21, 29, 32 and dependents are broadly drawn to any "single gene conversion" plant comprising one or more traits introgressed into the claimed variety by backcrossing or other traditional means, and methods of using these plants.

No guidance has been provided for the isolation or characterization of a multitude of heterologous coding sequences conferring a multitude of traits. In addition, no guidance has been provided for the introgression of any trait from a multitude of non-disclosed and uncharacterized parentals into the claimed variety, wherein said introgression should result in successful expression of the desired trait but should not interfere with the expression of the remaining traits whose combination confers patentability to the instantly exemplified variety, and which introgression should not introduce unwanted linked genetic material into the exemplified cultivar which would disrupt its patentably unique genetic complement. In addition, no guidance has been provided regarding the genetic or morphological characteristics of any of a multitude of breeding partners, or the resultant progeny.

Hunsperger et al (1996, U.S. Patent 5,523,520), Kraft et al (2000, Theor. Appl. Genet. 101:323-326), and Eshed et al (1996, Genetics 143:1807-1817) teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant. Hunsperger et al teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single gene conversion plant with a desired trait (see, e.g., column

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3, lines 26-46). In particular, Hunsperger et al teach that a gene conferring miniature plant stature which has been identified and genetically stabilized in one cultivar of *Petunia hybrida*, a member of the Solanaceae, does not confer a miniature phenotype when introgressed into the genome of a variety of other *Petunia hybrida* cultivars (see, e.g., column 3, lines 40-41).

Kraft et al teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotype-specific and loci-dependent in nature (see, e.g., page 323). Kraft et al teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is typically known about the plant breeding materials, which contributes to the unpredictability of the effect. Eshed et al teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (see, e.g., page 1815).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify and isolate the genes responsible for a multitude of non-exemplified traits, to evaluate the ability of these genes to be successfully expressed in various maize genetic backgrounds, or to obtain "single gene conversion" plants which contain a multitude of introgressed traits, but otherwise maintain all of the genetic and physiological and morphological characteristics of the parent plant. See also Applicant's traversal of the art rejection on page 8 of the amendment of 29 July 2002, where

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Applicant admits that outcrossing the exemplified hybrid to another undisclosed plant is unpredictable.

Claims 11, 15, 19, 24, 28 and 32 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dowden (U.S. Patent 5,880,339), as stated in the last office action.

Claims 1-10, 12-14, 16-18, 20-23, 25-27 and 29-31 are deemed free of the prior art, given the failure of the prior art to teach or suggest the particularly claimed maize plants with their unique complement of genotypic and morphological characteristics, or methods of using them, as argued in the amendment of 29 July 2002.

Claims 1-7 and 20 are allowed.

Applicant's arguments filed 29 July 2002, insofar as they pertain to the rejections above, have been fully considered but they are not persuasive.

Applicant urges that the indefiniteness rejection regarding "very high", "above average", etc. is improper, given the recitation in the claims of the particular ancestor of the plants and the recitation that the traits are "35Y54 traits", and given the data in the specification demonstrating particular values for these traits. The Examiner maintains that neither the individual traits nor their degree of expression nor their means of inheritance is unique to 35Y54.

Applicant urges that the indefiniteness rejection regarding "the maize breeding program of claim 9 [etc.]" is improper, since the term indeed possesses antecedent basis in the claims from which the rejected claims depend. The Examiner maintains that the rejected claims remain

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indefinite because they are drawn to a different category of invention than the claims from which they depend.

Applicant urges that the indefiniteness rejection regarding male sterility is improper, given the knowledge of the skilled artisan of various means of obtaining such sterility. The Examiner maintains that the claims are indefinite for simultaneously characterizing a male fertile plant as a male sterile one.

Applicant urges that the art rejection is improper, given the recitation of “35Y54 traits”, the ability of the artisan of ordinary skill to ascertain the breeding history and molecular profile of any plant containing “35Y54 traits”, the failure of the prior art to teach hybrid plants with all of the unique combination of traits and unique combination of genetics of 35Y54, and the failure of the prior art to teach or reasonably suggest the use of the exemplified hybrid as a starting material for the obtention of a maize plant with two of the claimed traits.

The Examiner maintains that the claimed individual traits are not unique to the exemplified hybrid, either in occurrence or level of expression or means of inheritance. Furthermore, Applicant has not disclosed any molecular markers associated with “35Y54 traits” or the specific 35Y54 genetic profile.

With regard to the unique genetic and morphological combination possessed by 35Y54, the Examiner concurs. However, the claims are not limited to 35Y54. Instead, the claims are broadly drawn to any descendant of 35Y54, produced by an unspecified number of generations of outcrossing to unspecified parents, wherein loss of 35Y54-derived genetic material would occur

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with each cross, wherein said descendant exhibits two traits also exhibited by 35Y54. Since the *individual* traits are not unique to 35Y54, either by degree of expression nor genetic means of inheritance, a descendant of 35Y54 containing no genetic material from 35Y54 could still exhibit these individual traits, and could still possess the same genetic means for conferring these traits as did 35Y54.

Furthermore, the Examiner maintains that the rejected claims are product-by-process claims, wherein the prior art teaches a product that is indistinguishable from the claimed product, despite the alternate methods of making the product. See *In re Thorpe* cited previously. Thus, the Examiner was not relying upon Dowden to teach the exemplified hybrid as a starting material.

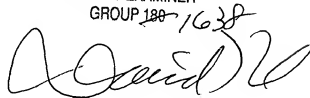
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

December 9, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

A handwritten signature in black ink, appearing to read "David T. Fox", is written over the printed name and group number.